Memo of Meeting

June 28, 2000

Rockville, MD

Representing the American Society for Quality:

Mr. Dan P. Olivier
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Certified Software Solutions, Inc.
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Mr. Bruce G. Haggar
Managing Partner
MedQ Systems, LLC
Palo Alto, CA 94301
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Representing the Food and Drug Administration:

Dr. Steven Solomon, ORA/OE, HFC-240, Part 11 Compliance Committee Chair
Paul J. Motise, ORA/OE, HFC-240, Committee Exec. Sec.
Stewart Crumpler, CDRH, OC, HFZ-343
John Murray, CDRH, OST, HFZ-141
Karen Moksnes, CDER/OC, HFD-320
James McCormack, ORA/OE, HFC-230
Tom Chin, ORA/OE, HFC-230
Jorge F. Christian, CVM/Compliance, HFV-232

The meeting was held at Mr. Olivier's request to discuss 21 CFR Part 11 and how the American Society for Quality (ASQ) could interact with and assist FDA in developing industry guidance on the rule.

Dr. Solomon explained the nature of the Part 11 Compliance Committee, the task it has in developing industry guidance, and that we welcomed the ASQ input into that process. We explained, however, that we could not collaborate with ASQ or other groups to jointly author documents.

Mr. Oliver and Mr. Haggar described ASQ as a non-profit association of about 100,000 individuals of which about 4,000 belong to the biomedical division of the group; ASQ has 22 divisions, two of which are primarily involved with FDA regulated industries. ASQ is considering developing a part 11 best practices document but does not have a formal vehicle for same (e.g., a document classification); the publication would therefore be a stand alone item. The ASQ representatives expressed the association's desire to help train and educate the industry (e.g., by conferences and publications) and described the group as a low cost provider. Mr. Haggar commented that conference attendance has declined in recent years, and like other organizations, ASQ is looking at alternative formats for delivering training (e.g. Internet-based training).

During the meeting we explained that FDA guidance would be developed in accordance with the agency's good guidance practices and the guidance could not countermand the regulations or the preamble.

ASQ representatives expressed concern about the fact that many device firms are now in violation of Part 11, especially with regard to their legacy systems. We explained how our enforcement policy takes all circumstances into account and that the compliance policy guide applies not to FD 483 observations, but to subsequent regulatory actions such as warning letters.

We discussed the importance of both technical and procedural controls in meeting part 11 and ensuring record integrity. We explained that part 11 does not permit firms to substitute procedural controls for the required technical controls. For example, administrative access controls and computer printouts do not exempt the corresponding electronic records from compliance with audit trail requirements.

We discussed the application of electronic record audit trails to various types of electronic records, including standard operating procedures, laboratory instrumentation, and process control systems. The ASQ representatives expressed concern that the medical device industry faced significant costs associated with revisions to their systems to bring them into compliance, especially if electronic audit trails are required for every piece of instrumentation that generates electronic data. We explained that part 11 requires audit trails for actions and entries of human beings that create, modify or delete electronic records. We commented that, as explained in comment # 72 of the preamble to the final rule, part 11 does not require audit trails for actions of automated devices. We added that any subsequent modifications and deletions made by humans to the electronic records created by those automated systems would need to be audit trailed. We agreed that agency guidance is needed in this area to clarify FDA expectations.

We commented that conformance with Part 11 would also help firms conform to mainstream electronic recordkeeping standards and requirements that have emerged in the domains of electronic commerce and electronic government. We briefly discussed the definition of electronic record and how the part 11 definition compared to that in the Electronic Signatures in Global and National Commerce Act (we gave them copies of the legislation.)

The meeting concluded after about two hours. There were no action items.

P. Motise

cc:

Part 11 Compliance Committee members (by e-mail)
HFA-224

P. Motise 6/28/00
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